



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(72) Inventors; and (75) Inventors/Applicants (for US only) : EKINS, Roger, Philip [GB/GB]; CHU, Frederick, Woodnam [GB/GB]; Department of Molecular Endocrinology, University College and Middlesex School of Medicine, Mortimer Street, London W1N 8AA (GB).			<b>Published</b> With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

**(54) Title: BINDING ASSAY EMPLOYING LABELLED REAGENT****(57) Abstract**

A binding assay process for an analyte, in which process a capture binding agent having binding sites specific for the analyte and a developing binding material capable of binding with the bound analyte or with the binding sites on the capture binding agent occupied by the bound analyte or with the binding sites remaining unoccupied on the capture binding agent are used, employs the capture binding agent in an amount such that only an insignificant fraction of the analyte in the sample becomes bound to the capture binding agent, the capture binding agent preferably being present at high surface density on microspots. A label is used in the assay in relation to the developing binding material, the label being provided by microspheres having a size of less than 5  $\mu\text{m}$  and carrying a marker, preferably fluorescent dye molecules contained within the microspheres. For determination of the concentration of the analyte in the sample the strength of the signal is representative of the fractional occupancy of the binding sites on the capture binding agent by the analyte and a comparison is made with a dose-response curve computed from standard samples. For detection of an analyte comprising a single-stranded DNA sequence the presence of the analyte is detected by the existence of a signal. A kit for the process comprises a solid support having the capture binding agent immobilised on it, a developing reagent comprising the developing binding material attached to the microspheres and, where concentrations are to be measured, standards having known amounts or concentrations of the analyte to be determined.

**PATENT COOPERATION TREATY**  
**PCT**

**INTERNATIONAL SEARCH REPORT**

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	<b>FOR FURTHER ACTION</b>		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)	
PCT/GB92/01892	15/10/92	15/10/91	
Applicant			

**MULTILYTE LIMITED et al.**

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.  
 It is also accompanied by a copy of each prior art document cited in this report.

1.  Certain claims were found unsearchable (see Box I).
2.  Unity of invention is lacking (see Box II).
3.  The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international search was carried out on the basis of the sequence listing
  - filed with the international application.
  - furnished by the applicant separately from the international application,
    - but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
  - Transcribed by this Authority
4. With regard to the title,  the text is approved as submitted by the applicant.  
 the text has been established by this Authority to read as follows:
5. With regard to the abstract,
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6. The figure of the drawings to be published with the abstract is:
 

Figure No. \_\_\_\_\_

  - as suggested by the applicant.
  - because the applicant failed to suggest a figure.
  - because this figure better characterizes the invention.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 92/01892

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)<sup>6</sup>

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.C1. 5 G01N33/543; G01N33/58; C12Q1/68

## II. FIELDS SEARCHED

Minimum Documentation Searched<sup>7</sup>

Classification System	Classification Symbols
Int.C1. 5	G01N ; C12Q

Documentation Searched other than Minimum Documentation  
to the Extent that such Documents are Included in the Fields Searched<sup>8</sup>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup>

Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
X	EP,A,0 396 801 (TEIKOKU HORMONE MFG CO., LTD) 14 November 1990 see the whole document ----	1-23
X	EP,A,0 360 088 (ABBOTT LABORATORIES) 28 March 1990 see page 3, line 40 - line 50 see page 6, line 1 - line 40; claims 10,11 ----	1-23
X	EP,A,0 301 584 (FUJIREBIO K.K) 1 February 1989 see the whole document ----	1-23
X	EP,A,0 267 317 (PROFILE DIAGNOSTIC SCIENCES INC.) 18 May 1988 see claims 1,3 ----	1-23 -/-

<sup>10</sup> Special categories of cited documents :<sup>10</sup><sup>"A"</sup> document defining the general state of the art which is not considered to be of particular relevance<sup>"E"</sup> earlier document but published on or after the international filing date<sup>"L"</sup> document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)<sup>"O"</sup> document referring to an oral disclosure, use, exhibition or other means<sup>"P"</sup> document published prior to the international filing date but later than the priority date claimed<sup>"T"</sup> later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention<sup>"X"</sup> document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step<sup>"Y"</sup> document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.<sup>"&"</sup> document member of the same patent family

## IV. CERTIFICATION

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Date of the Actual Completion of the International Search

29 JANUARY 1993

Date of Mailing of this International Search Report

17.02.93

International Searching Authority

EUROPEAN PATENT OFFICE

Signature of Authorized Officer

CARTAGENA ABELLA P

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
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A	WO,A,8 901 157 (R. PH. EKINS) 9 February 1989 cited in the application ---	
A	WO,A,8 401 031 (R. PH. EKINS) 15 March 1984 cited in the application -----	

**ANNEX TO THE INTERNATIONAL SEARCH REPORT  
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 9201892  
SA 65784

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 29/01/93

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